



**State-Level Impact:  
Leveraging SOTA Partnerships to  
Transform Opioid Treatment**

# Getting on the same page...

- Methadone
- Opioid Treatment Programs (OTPs)
- State Opioid Treatment Authorities (SOTAs)

## Role of the State Opioid Treatment Authority (SOTA) Core and Common Responsibilities under Current Federal Regulations May 2023

### BACKGROUND

In most states, the authority to oversee opioid treatment programs (OTPs) is granted to the Director of the State alcohol and drug agency, also known as the Single State Agency (SSA) for alcohol and other drugs. The specific responsibilities for overseeing OTPs are designated to a position that has come to be known as the State Opioid Treatment Authority, or the "SOTA."

*SOTAs play a key role ensuring accessible, high quality, and safe opioid disorder treatment in opioid treatment programs*

The Code of Federal Regulations Title 42, Part 8, *Medication Assisted Treatment for Opioid Use Disorder* specifies the rules by which OTPs must abide to legally operate. The same federal regulation outlines the responsibilities of a State agency in its oversight role of OTPs. In particular, the regulation designates "State Authority" as "the agency designated to exercise the responsibility and authority within the State Territory for governing the treatment of opioid addiction with an opioid drug."<sup>2</sup>

The Substance Abuse and Mental Health Services Administration (SAMHSA) certifies OTPs, accredits bodies, and supports education and training efforts to promote quality treatment services. The U.S. Drug Enforcement Administration (DEA) regulates controlled substances to prevent the diversion and misuse of medication provided in OTPs<sup>3</sup>, and plays a role in regulating OTPs.

### CORE RESPONSIBILITIES

The core responsibilities of the SOTA are outlined below.

- 1. Monitor OTPs' operations to ensure quality and regulatory compliance.** SOTAs oversee OTPs to ensure compliance with relevant federal and State laws and regulations, including conducting announced and unannounced visits. They provide technical assistance to assist OTPs in complying with federal and State requirements.
- 2. Serve as liaison between the OTPs and SAMHSA.** SOTAs collaborate closely with SAMHSA and the State licensing authority in processing applications for new OTPs. SAMHSA relies on the SOTAs to review and provide feedback on the ability of applicants for new OTPs to adhere to State and federal requirements. SOTAs help to inform OTPs about the requirements for accreditation and certification.
- 3. Serve as liaisons between the OTPs and the DEA.** SOTAs verify information to the DEA when an OTP applies for a new application, changes addresses, or when the DEA is reviewing an application for a medication unit.
- 4. Consult with and make recommendations to SAMHSA concerning new and renew applications for OTPs and medication units, and on patient complaints.** SOTAs meet with OTP applicants and visit the proposed site of the OTP to determine the acceptability of the program. The SOTA advises the OTP leadership about the roles of the DEA, SAMHSA, the SOTA, and the State.

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- 5. Review and approve or deny exception requests for SAMHSA approval, including requests to implement interim maintenance.** SOTAs are responsible for approving "exception requests" for take-home medications or other operational variances, based on the needs of the patients served by the OTP.
- 6. Educate partners about OTP services and medications for opioid use disorder.** In collaboration with State Directors, SOTAs are responsible for educating partners and stakeholders on the benefits of and operation of OTPs. This may include working closely with the State licensing staff, providing consultation regarding financial resources (such as Medicaid, insurance coverage or grant applications), and educating local government officials.
- 7. Oversee closure of OTPs to ensure regulatory compliance and continuity of care for patients.** SOTAs instruct OTPs that are terminating operations about federal and State regulations governing the closing of an OTP, including transfer of patient records to ensure that each patient impacted by the closing has a clear plan for continuity of care.
- 8. Act as a liaison for emergency and disaster planning.** SOTAs, in the case of emergencies and disasters, connect OTPs to the State's emergency preparedness agency for resources, as well as make the agency aware of the needs of the OTPs. The SOTA assures that OTPs have continuity of operations plan in place and are prepared to implement it should the need arise. SOTAs inform OTPs of their communication responsibilities in emergencies.

# Updates to 42 CFR Part 8 Opioid Treatment Regulations: General and Administrative Issues

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## These Changes Promote:



Fostering trust and recovery  
in a patient-centered  
environment



Acknowledging the skill and  
patient-centered  
understanding of treating  
practitioners



Creating responsive, flexible  
OTP services that are  
grounded in evidence



Promoting MOUD as a  
treatment for a chronic  
medical condition and  
reducing stigma

Administrators Session – Overview  
March 20, 2024, 2-3pm

Cultural Shifts In Care And Service Delivery

# Recent Federal-level Changes designed to lower barriers to methadone

*...this has been a  
MAJOR SHIFT*

- Take-home doses
- Telehealth (including audio-only buprenorphine induction)
- Mobile methadone
- 72-hour methadone from hospitals
- No counseling requirements

# Today's Conversation

## What it is...

- An opportunity to hear directly from state authorities about methadone reform in three different parts of the country

## What it is not...

- Time to get inside info on federal budgets, bills, reimbursement rates, SAMHSA's existence...